CLAIMS

1-45. (Canceled).

46. (Previously presented) A liquid pharmaceutical composition, comprising:

a follicle stimulating hormone or a variant thereof,

a diluent, and

at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68.

47. (Previously presented) The composition according to Claim 46, wherein the follicle stimulating hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

48. (Previously presented) The composition according to Claim 46, wherein the follicle stimulating hormone is present in an amount of from 300 IU/ml to 900 IU/ml.

49. (Previously presented) The composition according to Claim 46, wherein the follicle stimulating hormone is present in an amount of about 600 IU/ml.

50. (Previously presented) The composition according to Claim 46, wherein the surfactant is PLURONIC F68.

51. (Previously presented) The composition according to Claim 46, wherein the follicle stimulating hormone is human follicle stimulating hormone.

52. (Previously presented) The pharmaceutical composition according to Claim 46, wherein the follicle stimulating hormone is urinary human follicle stimulating hormone.

53. (Previously presented) The composition according to Claim 46, wherein the follicle stimulating hormone is recombinant human follicle stimulating hormone.

54. (Previously presented) The composition according to Claim 46, further comprising at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol.

55. (Previously presented) The composition according to Claim 46, further comprising m-cresol.

56. (Previously presented) The composition according to Claim 46, further comprising m-cresol in an amount of about 0.3% by mass based on the mass of the diluent.

57. (Previously presented) The composition according to Claim 46, further comprising sucrose.

58. (Previously presented) The composition according to Claim 46, further comprising methionine.

59. (Previously presented) The composition according to Claim 46, further comprising a phosphate buffer, wherein the pH of the composition is from 6.0 to 8.0.

60. (Previously presented) The composition according to Claim 46, further comprising a phosphate buffer, wherein the pH of the composition is about 7.0.

61. (Previously presented) The composition according to Claim 46, comprising the diluent, recombinant follicle stimulating hormone, PLURONIC F68, sucrose, methionine, m-cresol, and an aqueous buffer, and wherein the pH of the composition is about 7.0.

62. (Previously presented) The composition according to Claim 61, wherein the recombinant follicle stimulating hormone is present in an amount of about 600 IU/ml, the PLURONIC F68 is present in an amount of about 0.1 mg/ml, the sucrose is present in an amount of about 60 mg/ml, the methionine is present in an amount of about 0.1 mg/ml, the m-cresol is present in an amount of about 3 mg/ml, and the phosphate buffer is present in an amount of about 10 mM in phosphate.

63 . (Previously presented) The composition according to Claim 46, wherein the diluent is water for injection.

64 . (Previously presented) The composition according to Claim 46, wherein the diluent is at least one of water and a mixture of water with a solvent miscible with water.

65. (Previously presented) A liquid pharmaceutical composition, comprising:

a follicle stimulating hormone or a variant thereof,

a luteinising hormone or a variant thereof,

at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and

a diluent.

66. (Previously presented) The composition according to Claim 65, wherein the follicle stimulating hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

67. (Previously presented) The composition according to Claim 65, wherein the follicle stimulating hormone is present in an amount of from 300 IU/ml to 900 IU/ml.

68. (Previously presented) The composition according to Claim 65, wherein the follicle stimulating hormone is present in an amount of about 600 IU/ml.

69. (Previously presented) The composition according to Claim 65, wherein the luteinising hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

70. (Previously presented) The composition according to Claim 65, wherein the luteinising hormone is present in an amount of from 300 IU/ml to 750 IU/ml.

71. (Previously presented) The composition according to Claim 65, wherein the surfactant is PLURONIC F68.

72. (Currently amended) A liquid pharmaceutical composition, comprising:

a follicle stimulating hormone or a variant thereof,

a luteinising hormone or a variant thereof,

at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and

a diluent,

~~The composition according to Claim 65,~~ wherein the follicle stimulating hormone is human follicle stimulating hormone, the luteinising hormone is human luteinising hormone, or the follicle stimulating hormone is human follicle stimulating hormone and the luteinising hormone is human luteinising hormone.

73. (Currently amended) A liquid pharmaceutical composition, comprising:

a follicle stimulating hormone or a variant thereof,

a luteinising hormone or a variant thereof,

at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and

a diluent,

~~The pharmaceutical composition according to Claim 65,~~ wherein the follicle stimulating hormone is urinary human follicle stimulating hormone, the luteinising hormone is urinary human luteinising hormone, or the follicle stimulating hormone is urinary human follicle stimulating hormone and the luteinising hormone is urinary human luteinising hormone.

74. (Currently amended) A liquid pharmaceutical composition, comprising:

a follicle stimulating hormone or a variant thereof,

a luteinising hormone or a variant thereof,

at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and

a diluent,

~~The composition according to Claim 65,~~ wherein the follicle stimulating hormone is recombinant human follicle stimulating hormone, the luteinising hormone is recombinant human luteinising hormone, or the follicle stimulating hormone is recombinant human follicle stimulating hormone and the luteinising hormone is recombinant human luteinising hormone.

75. (Previously presented) The composition according to Claim 65, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 6:1 to 1:6.

76. (Previously presented) The composition according to Claim 65, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 4:1 to 1:2.

77. (Previously presented) The composition according to Claim 65, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 3:1 to 1:1.

78. (Previously presented) The composition according to Claim 65, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 2:1 to 1:1.

79. (Previously presented) The composition according to Claim 65, further comprising at least one bacteriostatic agent is selected from the group consisting of phenol and m-cresol.

80. (Previously presented) The composition according to Claim 65, further comprising m-cresol.

81. (Previously presented) The composition according to Claim 65, further comprising m-cresol in an amount of about 0.3% by mass based on the mass of the diluent.

82. (Previously presented) The composition according to Claim 65, further comprising sucrose.

83. (Previously presented) The composition according to Claim 65, further comprising methionine.

84. (Previously presented) The composition according to Claim 65, further comprising a phosphate buffer, wherein the pH of the composition is from 6.0 to 8.0.

85. (Previously presented) The composition according to Claim 65, further comprising a phosphate buffer, wherein the pH of the composition is about 7.0.

86. (Previously presented) The composition according to Claim 65, comprising the diluent, recombinant follicle stimulating hormone, PLURONIC F68, sucrose, methionine, m-cresol, and an aqueous buffer, wherein the pH of the composition is about 7.0.

87. (Previously presented) The composition according to Claim 86, wherein the recombinant follicle stimulating hormone is present in an amount of about 600 IU/ml, the

PLURONIC F68 is present in an amount of about 0.1 mg/ml, the sucrose is present in an amount of about 60 mg/ml, the methionine is present in an amount of about 0.1 mg/ml, the m-cresol is present in an amount of about 3 mg/ml, and the phosphate buffer is present in an amount of about 10 mM in phosphate.

88. (Previously presented) The composition according to Claim 65, wherein the diluent is water for injection.

89. (Previously presented) The composition according to Claim 65, wherein the diluent is at least one of water and a mixture of water and a solvent miscible with water.

90. (Withdrawn) A liquid pharmaceutical composition, comprising:

a diluent,

a luteinising hormone or a variant thereof, and

at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68.

91. (Withdrawn) The composition according to Claim 90, wherein the luteinising hormone is present in an amount of from 150 IU/ml to 1200 IU/ml.

92. (Withdrawn) The composition according to Claim 90, wherein the luteinising hormone is present in an amount of from 300 IU/ml to 750 IU/ml.

93. (Withdrawn) The composition according to Claim 90, wherein the surfactant is PLURONIC F68.

94. (Withdrawn) The composition according to Claim 90, wherein the luteinising hormone is human luteinising hormone.

95. (Withdrawn) The composition according to Claim 90, wherein the luteinising hormone is urinary human luteinising hormone.

96. (Withdrawn) The composition according to Claim 90, wherein the luteinising hormone is recombinant human luteinising hormone.

97. (Withdrawn) The composition according to Claim 90, further comprising at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol.

98. (Withdrawn) The composition according to Claim 90, further comprising m-cresol.

99. (Withdrawn) The composition according to Claim 90, further comprising m-cresol in an amount of about 0.3% by mass based on the mass of the diluent.

100. (Withdrawn) The composition according to Claim 90, further comprising sucrose.

101. (Withdrawn) The composition according to Claim 90, further comprising methionine.

102. (Withdrawn) The composition according to Claim 90, further comprising a phosphate buffer, wherein the pH of the composition is from 6.0 to 8.0.

103. (Withdrawn) The composition according to Claim 90, further comprising a phosphate buffer, wherein the pH of the composition is about 7.0.

104. (Withdrawn) The composition according to Claim 90, comprising: the diluent, recombinant luteinising hormone, PLURONIC F68, sucrose, methionine, m-cresol, and an aqueous buffer, and wherein the pH of the composition is about 7.0.

105. (Withdrawn) The composition according to Claim 90, wherein the recombinant luteinising hormone is present in an amount of about 600 IU/ml, the PLURONIC F68 is present in an amount of about 0.1 mg/ml, the sucrose is present in an amount of about 60 mg/ml, the methionine is present in an amount of about 0.1 mg/ml, the m-cresol is present in an amount of about 3 mg/ml, and the phosphate buffer is present in an amount of about 10 mM in phosphate.

106. (Withdrawn) The composition according to Claim 90, wherein the diluent is water for injection.

107. (Withdrawn) The composition according to Claim 90, wherein the diluent is at least of water and a mixture of water and a solvent miscible with water.

108. (Withdrawn) A freeze-dried composition, comprising:

a follicle stimulating hormone or a variant thereof, and

at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68.

109. (Withdrawn) The composition according to Claim 108, wherein the follicle stimulating hormone is present in an amount of from 0.1 to 10 μg/mg based on the total weight of the formulation.

110. (Withdrawn) The composition according to Claim 108, wherein the follicle stimulating hormone is present in an amount of from 0.3 to 5 μg/mg based on the total weight of the composition.

111. (Withdrawn) The composition according to Claim 108, wherein the follicle stimulating hormone is present in an amount of from 0.37 to 2 μg/mg based on the total weight of the composition.

112. (Withdrawn) The composition according to Claim 108, comprising PLURONIC F68.

113. (Withdrawn) The composition according to Claim 108, wherein the follicle stimulating hormone is human follicle stimulating hormone.

114. (Withdrawn) The composition according to Claim 108, wherein the follicle stimulating hormone is urinary human follicle stimulating hormone.

115. (Withdrawn) The composition according to Claim 108, wherein the follicle stimulating hormone is recombinant human follicle stimulating hormone.

116. (Withdrawn) The composition according to Claim 108, further comprising at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol.

117. (Withdrawn) The composition according to Claim 108, further comprising m-cresol.

118. (Withdrawn) The composition according to Claim 108, further comprising m-cresol in an amount of about 0.3% by mass.

119. (Withdrawn) The composition according to Claim 108, further comprising sucrose.

120. (Withdrawn) The composition according to Claim 108, further comprising methionine.

121. (Withdrawn) The composition according to Claim 108, further comprising a phosphate buffer.

122. (Withdrawn) The composition according to Claim 108, comprising: recombinant follicle stimulating hormone, PLURONIC F68, sucrose, methionine, m-cresol, and a buffer.

123. (Withdrawn) A freeze dried composition, comprising:

a luteinising hormone or a variant thereof, and

at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68.

124. (Withdrawn) The composition according to Claim 123, wherein the luteinising hormone is present in an amount of from 0.1 to 3 μg/mg based on the total weight of the composition.

125. (Withdrawn) The composition according to Claim 123, wherein the luteinising hormone is present in an amount of from 0.1 to 1 μg/mg based on the total weight of the composition.

126. (Withdrawn) The composition according to Claim 123, wherein the luteinising hormone is present in an amount of from 0.1 to 0.6 μg/mg based on the total weight of the composition.

127. (Withdrawn) The composition according to Claim 123, wherein the surfactant is PLURONIC F68.

128. (Withdrawn) The composition according to Claim 123, wherein the luteinising hormone is human luteinising hormone.

129. (Withdrawn) The composition according to Claim 123, wherein the luteinising hormone is urinary human luteinising hormone.

130. (Withdrawn) The composition according to Claim 123, wherein the luteinising hormone is recombinant human luteinising hormone.

131. (Withdrawn) The composition according to Claim 123, further comprising at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol.

132. (Withdrawn) The composition according to Claim 123, further comprising m-cresol.

133. (Withdrawn) The composition according to Claim 123, further comprising m-cresol in an amount of about 0.3% by mass.

134. (Withdrawn) The composition according to Claim 123, further comprising sucrose.

135. (Withdrawn) The composition according to Claim 123, further comprising methionine.

136. (Withdrawn) The composition according to Claim 123, further comprising a phosphate buffer.

137. (Withdrawn) The composition according to Claim 123, comprising recombinant luteinising hormone, PLURONIC F68, sucrose, methionine, m-cresol, and a buffer.

138. (Withdrawn) A freeze dried composition, comprising:

a follicle stimulating hormone or a variant thereof,

a luteinising hormone or a variant thereof, and

at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68.

139. (Withdrawn) The composition according to Claim 138, wherein the follicle stimulating hormone is present in an amount of from 0.3 to 5 μg/mg based on the total weight of the composition.

140. (Withdrawn) The composition according to Claim 138, wherein the follicle stimulating hormone is present in an amount of from 0.37 to 2 μg/mg based on the total weight of the composition.

141. (Withdrawn) The composition according to Claim 138, comprising PLURONIC F68.

142. (Withdrawn) The composition according to Claim 138, wherein the luteinising hormone is present in an amount of from 0.1 to 1 μg/mg based on the total weight of the composition.

143. (Withdrawn) The composition according to Claim 138, wherein the luteinising hormone is present in an amount of from 0.1 to 0.6 μg/mg based on the total weight of the composition.

144. (Withdrawn) The composition according to Claim 138, wherein the follicle stimulating hormone is human follicle stimulating hormone, the luteinising hormone is human luteinising hormone, or the follicle stimulating hormone is human follicle stimulating hormone and the luteinsing hormone is human luteinising hormone.

145. (Withdrawn) The composition according to Claim 138, wherein the follicle stimulating hormone is urinary human follicle stimulating hormone, the luteinising hormone is urinary human luteinising hormone, or the follicle stimulating hormone is urinary human follicle stimulating hormone and the luteinsing hormone is urinary human luteinising hormone.

146. (Withdrawn) The composition according to Claim 138, wherein the follicle stimulating hormone is recombinant human follicle stimulating hormone, the luteinising hormone is recombinant human luteinising hormone, or the follicle stimulating hormone is recombinant human follicle stimulating hormone and the luteinsing hormone is recombinant human luteinising hormone.

147. (Withdrawn) The composition according to Claim 138, further comprising at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol.

148. (Withdrawn) The composition according to Claim 138, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 6:1 to 1:6.

149. (Withdrawn) The composition according to Claim 138, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 4:1 to 1:2.

150. (Withdrawn) The composition according to Claim 138, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 3:1 to 1:1.

151. (Withdrawn) The composition according to Claim 138, wherein the follicle stimulating hormone and the luteinising hormone are present in a ratio of from 2:1 to 1:1.

152. (Withdrawn) The composition according to Claim 138, further comprising m-cresol.

153. (Withdrawn) The composition according to Claim 138, further comprising m-cresol in an amount of about 0.3% by mass.

154. (Withdrawn) The composition according to Claim 138, further comprising sucrose.

155. (Withdrawn) The composition according to Claim 138, further comprising methionine.

156. (Withdrawn) The composition according to Claim 138, further comprising a phosphate buffer.

157. (Withdrawn) The composition according to Claim 138, comprising recombinant follicle stimulating hormone, PLURONIC F68, sucrose, methionine, m-cresol, and a buffer.

158. (Withdrawn) The composition according to Claim 138, comprising

32.75 μg of recombinant follicle stimulating hormone, 9.0 μg of recombinant luteinising hormone, 15.0 mg of sucrose, 0.052 mg of $NaH_2PO_4H_2O$, 0.825 mg of Na_2HPO_4 2 H_2O, 0.5 mg of PLURONIC F68 and 0.05 mg of L-methionine.

159. (Withdrawn) The composition according to Claim 138, comprising

65.5 μg of recombinant follicle stimulating hormone, 18.0 μg of recombinant luteinising hormone, 30.0 mg of sucrose, 0.104 mg of $NaH_2PO_4H_2O$, 1.65 of Na_2HPO_4 2 H_2O, 0.10 mg of PLURONIC F68 and 0.10 mg of L-methionine.

160. (Withdrawn) A method for manufacturing a pharmaceutical composition, comprising:

mixing a follicle stimulating hormone, at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and a liquid diluent,

to form a solution.

161. (Withdrawn) The method according to Claim 160, wherein the surfactant is PLURONIC F68.

162. (Withdrawn) The method according to Claim 160, further comprising:

mixing at least one bacteriostatic agent selected from the group consisting of phenol and m-cresol, with the follicle stimulating hormone, the surfactant and the liquid diluent.

163. (Withdrawn) A method for manufacturing a packaged pharmaceutical composition, comprising:

placing a solution comprising a follicle stimulating hormone, a diluent and at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68,

into at least one of a vial, ampoule and cartridge.

164. (Withdrawn) The method according to Claim 163, wherein the surfactant is PLURONIC F68.

165. (Withdrawn) A kit, comprising:

a first container containing a freeze-dried composition comprising a follicle stimulating hormone or a variant thereof, and at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and

a second container containing a diluent for reconstituting the freeze-dried composition.

166. (Withdrawn) The kit according to Claim 165, wherein the second container contains an aqueous diluent comprising m-cresol.

167. (Withdrawn) A kit, comprising:

a first container containing a freeze-dried composition comprising a luteinising hormone or a variant thereof, and at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and

a second container containing a diluent for reconstituting the freeze-dried composition.

168. (Withdrawn) The kit according to Claim 167, wherein the second container contains an aqueous diluent comprising m-cresol.

169. (Withdrawn) A kit, comprising:

a first container containing a freeze-dried composition comprising a follicle stimulating hormone or a variant thereof, a luteinising hormone or a variant thereof, and at least one surfactant selected from the group consisting of PLURONIC F77, PLURONIC F87, PLURONIC F88 and PLURONIC F68, and

a second container containing a diluent for reconstituting the freeze-dried composition.

170. (Withdrawn) The kit according to Claim 169, wherein the second container contains an aqueous diluent comprising m-cresol.

171. (Withdrawn) A method for manufacturing the freeze-dried formulation according to Claim 108, comprising:

mixing the follicle stimulating hormone and the surfactant and subjecting the mixture to lyphilisation.

172. (Withdrawn) The method according to Claim 171, wherein the surfactant is PLURONIC F68.

173. (Withdrawn) A method for manufacturing a freeze-dried formulation according to Claim 123, comprising:

mixing the luteinising hormone and the surfactant, and

subjecting the mixture to lyphilisation.

174. (Withdrawn) The method according to Claim 173, wherein the surfactant is PLURONIC F68.

175. (Withdrawn) The method for manufacturing the composition according to Claim 138, comprising:

mixing the follicle stimulating hormone, the luteinising hormone, and the surfactant, and

subjecting the mixture to lyphilisation.

176. (Withdrawn) The method according to Claim 175, wherein the surfactant is PLURONIC F68.

177. (Withdrawn) A method for treating infertility, comprising:

administering the composition according to Claim 46 to a human in an effective amount.

178. (Withdrawn) The method according to Claim 177, wherein the follicle stimulating hormone is administered in an amount of from 150-600 IU.

179. (Withdrawn) A method for treating infertility, comprising:

administering the composition according to Claim 65 to a human in an effective amount.

180. (Withdrawn) The method according to Claim 179, wherein one or both of the follicle stimulating hormone and the luteinising hormone is administered in an amount of from 150 – 600 IU.

181. (Withdrawn) A method for treating infertility, comprising:

administering the composition according to Claim 90 to a human in an effective amount.

182. (Withdrawn) The method according to Claim 181, wherein the luteinising hormone is administered in an amount of from 150-600 IU.

183. (Withdrawn) A method for treating infertility, comprising:

reconstituting the freeze-dried composition according to Claim 108 in a liquid diluent; and

administering the reconstituted composition to a human in an effective amount.

184. (Withdrawn) The method according to Claim 183, wherein the follicle stimulating hormone is administered in an amount of from 150 to 600 IU.

185. (Withdrawn) A method for treating infertility, comprising:

reconstituting the freeze-dried composition according to Claim 123 with a liquid diluent; and

administering the reconstituted composition to a human in an effective amount.

186. (Withdrawn) The method according to Claim 185, wherein the luteinising hormone is administered in an amount of from 150-600 IU.

187. (Withdrawn) A method for treating infertility, comprising:

reconstituting the freeze-dried composition according to Claim 138 with a liquid diluent; and

administering the reconstituted composition to a human in an effective amount.

188. (Withdrawn) The method according to Claim 185, wherein one or both of the follicle stimulating hormone and the luteinising hormone is administered in an amount of from 150-600 IU.